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09/315,918 05/20/99 CHAN

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| EXAMINER |
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| ART UNIT | PAPER NUMBER |
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3732

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DATE MAILED:

09/08/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/315,918

Applicant(s)

Chan

Examiner

Eduardo C. Robert

Group Art Unit

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☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-28 is/are pending in the application.

Of the above, claim(s) 25-28 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-24 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claim 17 is rejected under 35 U.S.C. 101 because it is drawn to non-statutory subject matter. In claim 17, line 4, applicant positively recites part of a human, i.e. "said body is fixed in the bone tunnel". Thus claim 17 includes a human within their scope and is non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.d. 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 1-17 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. An interference screw is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhem*, 527 F.d. 1229, 188 USPQ 356 (CCPA 1976). It is noted that claim 1 recites "An apparatus for fixing a ligament or tendon in a bone tunnel" and the "apparatus" comprising a "jamming retainer". However, as disclosed, it appears that the "jamming retainer" can not achieve by itself the functional recitation of "fixing a ligament or tendon in a bone tunnel" (see page 10, lines 2-4). Furthermore, it is noted that the "interference screw" is what appears to fix, trap, or keep the jamming retainer and ligament or tendon in a bone tunnel as disclosed by applicant (see page 10, lines 5-21; page 11, line 21, through page 12, line 19; figures 18, 20, 30; etc.) . Therefore, if applicant's intention is to claim the "jamming retainer" alone, it is recommended that the preamble "for fixing a ligament or tendon in a bone tunnel" be changed to -- for augmenting an interference screw fixation of a ligament in a bone tunnel, whereby resistance to slippage of the ligament is improved, said apparatus --.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 13 and 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is an improper dependent claim because it does not further limit the structure of the apparatus of claim 12, i.e. a jamming retainer which is rigid and has a bore **configure to** receive a suture retainer, but merely recite a limitation of the "suture retainer" which is not positively recited in claim 12.

There exists an inconsistency between the language of claim 12 and that of the claim 15 dependent thereon, thus making the scope of the claim unclear. In claim 12, applicant recites an apparatus comprising a jamming retainer with the "suture retainer" being only functionally recited, i.e. "configured to receive a suture retainer", thus indicating that the claim is directed to the subcombination, an apparatus comprising a jamming retainer. However, in claim 15, applicant positively recites the "suture retainer" as part of the invention, i.e. "said suture retainer and said bore configured to bind suture received therebetween", thus indicating that the combination, apparatus comprising a jamming retainer and suture retainer, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claims 12-17 will be considered as being drawn to the combination, an apparatus comprising a jamming retainer and a suture retainer.

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In claim 16, line 1, "said body" lacks a prior antecedent.

In claim 17, line 4, "said body" lacks a prior antecedent.

Claim 25 is an improper dependent claim because it refers to itself and thus has been withdrawn from consideration.

Claims 26-28 depend from claim 25 which has been withdrawn from consideration. Therefore, claims 26-28 also are withdrawn from consideration.

Specification

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an adequate written description of the invention and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure. It is unclear from applicant's disclosure how a jamming retainer fix a ligament or tendon in a bone (claim 1). Also see the reasons set forth in the 112 rejection above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

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has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 3, 12, 13-18, as understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Curtis, et al.

Curtis, et al. disclose an apparatus represented in figures 1 and 2 comprising a jamming retainer 11 having a longitudinal bore. The apparatus further comprises a suture retainer 14 which has a tapered shape and is received in the longitudinal bore of the jamming retainer 11 (see col. 2, lines 35-37). The apparatus can be made from stainless steel or titanium (see col. 3, lines 16-18). Curtis, et al. further disclose that the apparatus is used with a suture that attaches a soft tissue to bone, and that the jamming retainer retains the suture and soft tissue and the jamming retainer is secured to the bone (see col. 1, lines 5-19, and col. 2, lines 20-40).

Claims 1, 2, 9-11, as understood, are rejected under 35 U.S.C. 102(e) as being anticipated by Boucher, et al.

Boucher, et al. disclose an apparatus comprising a jamming retainer 116 fixed in a bone tunnel with an interference screw 152. The jamming retainer 116 has exterior threads which correspond to threads of the interference screw 152. The jamming retainer is tapered (see Figure 7).

Claims 1-4, 6, 8-11, and 18-24, as understood, are rejected under 35 U.S.C. 102(e) as being anticipated by Beck, Jr., et al.

Beck, Jr., et al. disclose an apparatus comprising a jamming retainer which is fixed in a bone tunnel with an interference screw (see Figures 1, 3, and 5). The jamming retainer has a

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longitudinal bore (see Figure 2). In one embodiment the jamming retainer has grooves 25 and hole or recess 20 that in combination forms a loop for receiving a ligament or tendon (see Figure 1). The jamming retainer has exterior threads which correspond to threads of the interference screw. The jamming retainer can be tapered (see col. 8 , lines 10-11). Beck, Jr., et al. further disclose a method comprising the steps: retaining a ligament or tendon with a jamming retainer; securing a jamming retainer in a bone tunnel; pulling a jamming retainer through the bone tunnel with a suture (see Figure 3); pushing a jamming retainer through the bone tunnel with an inserter (see Figure 2); introducing a ligament or tendon into a traverse hole or bore in the jamming retainer; introducing an interference screw into a bone tunnel.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beck, Jr., et al.

Beck, Jr., et al. disclose the claimed invention except for the jamming retainer having a spherical shape. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the jamming retainer of Beck, Jr., et al. having a spherical shape, since applicant has not disclosed that such solve any stated problem or is anything

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more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of enhance fixation of a ligament in a bone tunnel. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Claims 4-6, 14, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curtis, et al. in view of Pierce.

Curtis, et al. disclose the claimed invention except for a loop for receiving a ligament or tendon. Pierce discloses a jamming retainer 15 with a suture B to retain ligament, tendons, or soft tissue. The suture B is formed in a loop to held fast the soft tissue to the bone (see Figure 31). It would have been obvious to one skilled in the art at the time the invention was made to make a loop with the suture of Curtis, et al. in view of Pierce, in order to ensure that the soft tissue is held to the bone.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Thal; Roger, et al.; Goble, et al.; Lehmann; Chervitz, et al.; Martins; and Bramlet are cited art of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is (703) 305-7333.



E.C. Robert

September 3, 1999



JEFFREY A. SMITH
PRIMARY EXAMINER